

MODEL STANDING ORDERS

***Haemophilus influenzae* Type b (Hib) Conjugate Vaccine**

These model standing orders are current as of April 2004. They should be reviewed carefully against the most current recommendations and may be revised by the clinician signing them.

Hib vaccine is indicated for the following groups:

- all infants and children less than 59 months of age. The number of doses needed is dependent on the age of the child when the vaccine series is initiated and the type of vaccine given;
- unimmunized children ≥ 5 years of age with sickle-cell disease, HIV infection, AIDS, severe non-HIV immunosuppressive condition and treatments, functional or anatomic asplenia, renal failure and diabetes;
- adults with severe non-HIV immunosuppression, after organ transplantation with functional or anatomic asplenia and chronic immunosuppressive therapy.

Hib vaccine may be considered for the following groups:

- adults with HIV infection and AIDS;
- adults with functional or anatomic asplenia;
- adults with renal failure;
- adults with diabetes;
- adults with alcoholism and alcoholic cirrhosis.

ORDER:

1. Provide patient, parent or legal representative with a copy of the Vaccine Information Statement (VIS) and answer any questions.
2. Screen for contraindications according to Table 1.
3. Give Hib vaccine 0.5 ml intramuscularly (IM) according to the recommended schedule (see Table 2). **Always check the package insert prior to administration of any vaccine.** Administer IM vaccines at a 90° angle with a 22- to 25-gauge needle.
 - a. For infants ≤ 12 months of age, administer into the anterolateral aspect of the thigh with a 7/8- to 1-inch needle. (For newborn and or low birth weight infants only, a 5/8" needle may be considered.)
 - b. For children ≥ 12 months of age, administer into the anterolateral aspect of the thigh or deltoid muscle, using a 7/8- to 1¼-inch needle, depending on the size of the needle.
 - c. For adolescents and adults, administer in the deltoid using a 1- to 2-inch needle, depending on the vaccine recipient's weight (1 inch for females < 70 kg; 1.5 inches for females 70-100 kg; 1 to 1.5 inches for males ≤ 120 kg; and 2 inches for males > 120 kg and females > 100 kg).

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Vaccine should be given according to the correct schedule for age and number of previous doses received.

- For the schedules for unimmunized children receiving Hib TITER™ (HbOC), ActHib™ and OmniHib™ (PRP-T), please refer to Tables 2 and 3.
 - For the catch up schedule for partially immunized children not up-to-date and receiving any formulation, please refer to Table 4.
 - For the schedules for unimmunized children receiving PedvaxHib™ (PRP-OMP), please refer to Attachment 1.
 - The primary vaccine series should be completed with the same Hib vaccine, if feasible. However, if different infant formulations (i.e., PRP-OMP, PRP-T, HbOC) are administered, a total of three doses of Hib vaccine is considered adequate for the primary series among infants.
4. Administer Hib simultaneously with all other vaccines indicated, according to the recommended schedule and patient's vaccine status.
 5. If possible, observe patient for an allergic reaction for 15 – 20 minutes after administering vaccine.
 6. Facilities and personnel should be available for treating immediate hypersensitivity reactions.
 7. Report clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967, or via the VAERS website: www.vaers.org.
 8. Please see the MIP document, *General Protocols for Standing Orders*, for further recommendations and requirements regarding vaccine administration, documentation, and consent.

Hib Vaccine Storage and Handling After Reconstitution
<ul style="list-style-type: none">• ActHIB® vaccine must be used \leq 24 hours after reconstitution, or be discarded.• Tripedia®-ActHIB® [TriHIBIT®] vaccine must be used \leq 30 minutes after reconstitution, or be discarded.

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Table 1. Contraindications and Precautions to Hib Vaccine

Valid Contraindications to Hib	Invalid Contraindications to Hib (Hib Vaccine should be administered)
Anaphylactic reaction to a previous dose of Hib, latex (PedvaxHIB™, HibTITER®), and the vial of <u>diluent</u> for ActHib®)¹ or to any other component of the vaccine (see package insert for specific components)¹	Non-anaphylactic allergy to any component of the vaccine
	Mild illness with or without a low-grade fever
	Local reaction to previous dose of Hib
	Current antimicrobial therapy
	Pregnancy
Precaution to Hib Vaccine: <ul style="list-style-type: none"> Moderate to severe illness with or without fever (temporary precaution) 	Convalescent phase of illness
	Recent exposure to infectious disease
	Prematurity (same dose & schedule as full-term infants)
	Personal or family history of nonspecific allergies
	History of Hib disease

¹ Persons with a history of anaphylaxis to a vaccine component, but who are at high risk for Hib disease, should be referred to a health care provider for evaluation and possible administration of Hib vaccine.

HibTITER® (HbOC), ActHib® and OmniHib™ (PRP - T) Schedules for Unimmunized Children Without Any Previous Doses

Table 2. Hib Schedule for Children Without Any Previous Doses

Age Receiving 1st Dose	Dose	Recommended Age	Accelerated Schedule
0 – 7 months	1 ¹	2 months	≥ 6 weeks of age
	2 ¹	4 months	≥ 1 month after 1 st dose
	3 ¹	6 months	≥ 1 month after 2 nd dose
	4	12 – 15 months	≥ 2 months after previous dose and ≥ 12 months of age
7 – 11 months	1 ¹	-	1 st visit
	2 ¹	-	≥ 1 month after 1 st dose
	3 ¹	-	≥ 2 months after previous dose and between 12 - 15 months of age
12 – 14 months	1 ²	-	1 st visit
	2 ²	-	≥ 2 months after previous dose
15 – 59 months	1	-	1 st visit

¹ When feasible, use same vaccine for doses 1 – 3.

² When feasible, use same vaccine for doses 1 – 2.

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Table 3. Hib Schedule for Individuals 60 Months of Age or Older with Chronic Conditions Associated with an Increased Risk of Hib Disease

Hib vaccine is **not** routinely administered to healthy children after their 5th birthday. However, it is indicated for children included in groups outlined on page 1.

Doses	Accelerated Schedule ¹
1 or 2	1 st visit; dose 2 (if indicated) given 2 months later

¹ Two doses are suggested for children with HIV infection and IgG₂ deficiencies. Some experts also believe a “booster” reinforcing dose should be given to children undergoing treatment for malignancies ≥ 3 months after completion of all chemotherapy.

Table 4. Hib Schedule (All Hib Formulations) for Partially-Immunized Children, Not Up-To-Date

Age at Presentation	Previous Vaccination History	Recommended Regimen
7- 11 months	1 dose of HbOC, PRP-T, or PRP-OMP ¹ 2 doses of HbOC or PRP-T	1 dose of conjugate at 7- 11 months with a booster dose given at least 2 months later, at 12- 15 months ² Same as above
12- 14 months	2 doses before 12 months of HbOC, PRP-T or PRP- OMP ¹	1 dose of any licensed conjugate ^{3,4}
12- 14 months	1 dose before 12 months of HbOC, PRP-T or PRP- OMP ¹	2 additional doses of any licensed conjugate, with a minimum interval of 2 months ^{3,4}
15- 59 months	Any incomplete schedule	1 dose of any licensed conjugate ^{3,4}

¹ HbOC (HibTITER[®]), PRP-T (ActHIB[®], OmniHIB[™]), PRP-OMP (PedvaxHIB[™]).

² For the dose given at 7- 11 months, when feasible, the same vaccine should be used for the dose given at 2- 6 months. At ≥ 12 months of age, any licensed conjugate can be used.

³ After 12 months of age, PRP-D (*ProHIBit*) may also be used (in addition to formulations in footnote 1).

⁴ For children 12- 59 months of age with an underlying condition predisposing them to Hib disease who are not immunized or who have received only 1 dose of conjugate vaccine before 12 months, 2 additional doses of a licensed conjugate vaccine (separated by 2 months) are recommended. If they have received 2 doses before 12 months, only 1 dose is recommended.

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References:

ACOG (American College of Obstetricians and Gynecologists). Immunization During Pregnancy. ACOG Committee Opinion No. 282, January 2003.

American Academy of Pediatrics. Active and Passive Immunization. *Haemophilus Influenzae* Infections. Immunization in Special Clinical Circumstances. Standards for Child and Adolescent Immunization Practices (Appendix II). In: Pickering LK, ed. *Red Book: 2003 Report of the Committee on Infectious Diseases*. 26th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2003: 7-53, 53-66, 293-301, 66-93, 795-798.

CDC. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Family Physicians (AAFP). MMWR 2002; 51 (No. RR-2):1-35.

CDC. Guide to contraindications to vaccines. U.S. Department of Health & Human Services, September 2003.

CDC. *Haemophilus* b conjugate vaccines for prevention of *Haemophilus influenzae* type b disease among infants and children two months of age and older: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1991; 40 (No. RR-1): 1-7.

CDC. Recommendations of the Advisory Committee on Immunization Practices (ACIP): use of vaccines and immune globulins in persons with altered immunocompetence. MMWR 1993; 42 (No. RR-4): 1-18.

CDC. Recommended adult immunization schedule – United States, 2003-2004. MMWR 2003;52:965-969.

CDC. Recommended childhood and adolescent immunization schedule - United States, Jan – June 2004. MMWR 2004;53:Q1-Q4.

National Vaccine Advisory Committee. Standards for child and adolescent immunization practices. Pediatrics 2003;112:958-963.

Poland GA, Shefer AM, McCauley M, Webster, PS, Whitley-Williams PN, Peter G, and the National Advisory Committee. Standards for adult immunization practices. Am J Prev Med 2003;25:144-150.

Massachusetts Department of Public Health

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MODEL STANDING ORDERS***Haemophilus b* Conjugate Vaccine (Hib)****Attachment 1****PedvaxHib™ (PRP - OMP) Schedules for Unimmunized Children Without Any Previous Doses****Table A. Hib Schedule for Children Without Any Previous Doses**

Age Receiving 1 st Dose	Dose	Recommended Age	Accelerated Schedule
0 – 7 months	1 ¹	2 months	≥ 6 weeks of age
	2 ¹	4 months	≥ 1 month after 1 st dose
	3	12 – 15 months	≥ 2 months after previous dose and ≥ 12 months of age
7 – 11 months	1	-	1 st visit
	2	-	≥ 1 months after 1 st dose
	3	-	≥ 2 months after previous dose and between 12 – 15 months of age
12 – 14 months	1	-	1 st visit
	2	-	2 months after the previous dose
15 – 59 months	1	-	1 st visit

¹ When feasible, use the same vaccine for doses 1 – 2.

Table B. Hib Schedule for Individuals 60 Months of Age or Older with Chronic Conditions Associated with an Increased Risk of Hib Disease

Hib vaccine is **not** routinely administered to healthy children after their 5th birthday. However, it is indicated for children included in groups outlined on page 1.

Doses	Accelerated Schedule
1 or 2	1 st visit; dose 2 (if indicated) given 2 months later

¹ Two doses are suggested for children with HIV infection and IgG₂ deficiencies. Some experts also believe a “booster” reinforcing dose should be given to children undergoing treatment of for malignancies ≥3 months after completion of all chemotherapy.

Please refer to **Table 4: Hib Schedule (All Formulations) for Partially-Immunized Children, Not Up-To-Date** on page 4.

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